

December 11, 2000

Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington D.C. 20204

**NOTIFICATION OF STATEMENT(S)
OF NUTRITIONAL SUPPORT**

This notification is filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (FDC Act), 21 U.S.C. Section 343(r)(6).

Name of Dietary Supplement: **Antioxidant Supreme™**
Statement of Nutritional Support: Combats Free Radicals;
Combines essential vitamins with key herbs well-known
for their high level of free radical scavenger activity;
Provides an advanced level of antioxidant support

Name of Dietary Supplement: **Bilberry Vision Complex**
Statement of Nutritional Support: Promotes Eye Health;
Promotes healthy eye function

Name of Dietary Supplement: **Bitters With Ginger**
Statement of Nutritional Support: Promotes Digestion;
Stimulates digestive enzymes for better digestion

Name of Dietary Supplement: **Black Walnut Complex**
Statement of Nutritional Support: Promotes Gastrointestinal Health

Name of Dietary Supplement: **Bladdex™**
Statement of Nutritional Support: Promotes A Healthy Genito-Urinary Tract



Name of Dietary Supplement:	Brainstorm 2™
Statement of Nutritional Support:	Promotes Mental Clarity; Promotes mental concentration
Name of Dietary Supplement:	Breast Health with Maitake Bio-Beta-Glucan™
Statement of Nutritional Support:	Promotes Breast Health; Balances female health; Advanced antioxidant and immune-enhancing properties
Name of Dietary Supplement:	Broncitone™
Statement of Nutritional Support:	Promotes Healthy Lungs
Name of Dietary Supplement:	Cranberry, Super
Statement of Nutritional Support:	Promotes Urinary Tract Health
Name of Dietary Supplement:	Detox Formula
Statement of Nutritional Support:	Promotes Natural Cleansing; Promotes natural detoxification of the body; Provides antioxidant support
Name of Dietary Supplement:	Di-Jest™
Statement of Nutritional Support:	Promotes A Healthy Digestive Process; Supports the gastrointestinal tract for healthy digestion
Name of Dietary Supplement:	Echinacea with Astragalus
Statement of Nutritional Support:	Promotes A Healthy Body; Enhances immune function; Tones the body systems
Name of Dietary Supplement:	Echinacea with Ester-C®
Statement of Nutritional Support:	Promotes Immune Health; Supports the body's natural defense systems; Immune-stimulating
Name of Dietary Supplement:	Echinacea Herb/Root and Goldenseal Root
Statement of Nutritional Support:	Strengthens Immune Functions; Supports mucous membranes; Keeps the body's natural defense mechanisms healthy
Name of Dietary Supplement:	Echinacea with Maitake Bio-Beta-Glucan™
Statement of Nutritional Support:	Stimulating Immune Tonic; Promotes positive actions on the body's natural defense systems; Stimulates the immune system



Name of Dietary Supplement:
Statement of Nutritional Support:

Female Complex™
Promotes Female Hormonal Balance

Name of Dietary Supplement:
Statement of Nutritional Support:

Garlic, Super Complex
Promotes Cardiovascular Health;
Provides micronutrients essential to the body;
Plays a key role in promoting heart health, stimulating
the circulatory system and providing general antioxidant
protection; Features a blend of Garlic with
Vitamin E, plus key herbs recognized for their positive
actions on the cardiovascular system.

Name of Dietary Supplement:
Statement of Nutritional Support:

Liver Support
Promotes A Healthy Liver

Name of Dietary Supplement:
Statement of Nutritional Support:

Male Complex™
Promotes Sexual Health

Name of Dietary Supplement:
Statement of Nutritional Support:

Mood Balance
Promotes Emotional Well-Being;
Promotes emotional health and a positive sense of
well-being

Name of Dietary Supplement:
Statement of Nutritional Support:

ProstSupport™
Promotes Prostate Health;
High in nutrients which provide antioxidant activities

Name of Dietary Supplement:
Statement of Nutritional Support:

Sambucus and Ester-C®
Promotes A Healthy Respiratory System

Name of Dietary Supplement:
Statement of Nutritional Support:

Sambucus and Maitake Bio-Beta-Glucan™
Promotes A Healthy Body;
Promotes positive actions on the respiratory system;
Stimulates the immune system

Name of Dietary Supplement:
Statement of Nutritional Support:

Slumber™
Promotes Restful Sleep;
Promotes relaxation and sleep

Name of Dietary Supplement:
Statement of Nutritional Support:

Tense-Ease™
Promotes Stressless Moments;
Supports and nourishes the central nervous system;
Helps encourage a more relaxed "state of mind"



Name of Dietary Supplement:	Alfalfa Leaf
Statement of Nutritional Support:	Promotes Overall Wellness
Name of Dietary Supplement:	Aloe Vera Phytogel
Statement of Nutritional Support:	Soothes The Digestive Tract
Name of Dietary Supplement:	Astragalus Root
Statement of Nutritional Support:	Promotes A Healthy Body; Invigorates vital energy (qi); Maintains wellness
Name of Dietary Supplement:	Barley Grass
Statement of Nutritional Support:	Promotes Overall Wellness
Name of Dietary Supplement:	Black Cohosh Root
Statement of Nutritional Support:	Promotes Female Hormonal Balance
Name of Dietary Supplement:	Bladderwrack Thallus
Statement of Nutritional Support:	Promotes Weight Loss; Balances thyroid function
Name of Dietary Supplement:	Burdock Root
Statement of Nutritional Support:	Promotes Healthy Blood; Promotes detoxification
Name of Dietary Supplement:	Butcher's Broom Root
Statement of Nutritional Support:	Promotes Vascular Tone; Natural support for improving elasticity and tone of vascular tissue
Name of Dietary Supplement:	Cascara Sagrada Bark
Statement of Nutritional Support:	Promotes A Laxative Action
Name of Dietary Supplement:	Cat's Claw Inner Bark
Statement of Nutritional Support:	Promotes Immune Function; Helps digestion, enhances immune function and detoxifies the body
Name of Dietary Supplement:	Cayenne Pepper Fruit
Statement of Nutritional Support:	Promotes Healthy Circulation; Helps the body combat free radicals



Name of Dietary Supplement:
Statement of Nutritional Support:

Chamomile Flower
Promotes Digestive Comfort
Historically used as a relaxing herb at bedtime

Name of Dietary Supplement:
Statement of Nutritional Support:

Chinese Goldenseal Root
Promotes Healthy Mucous Membranes;
Serves as a natural aid for digestion

Name of Dietary Supplement:
Statement of Nutritional Support:

Cranberry Fruit
Promotes Urinary Tract Health

Name of Dietary Supplement:
Statement of Nutritional Support:

Damiana Leaf
Promotes Sexual Health;
Promotes relaxation

Name of Dietary Supplement:
Statement of Nutritional Support:

Dandelion Root
Promotes A Healthy Liver;
Serves as a diuretic

Name of Dietary Supplement:
Statement of Nutritional Support:

Dong Quai Root
Promotes Female Hormonal Balance;
Helps regulate the female system and balance hormones

Name of Dietary Supplement:
Statement of Nutritional Support:

Echinacea Herb
Promotes A Healthy Immune System

Name of Dietary Supplement:
Statement of Nutritional Support:

Echinacea Root
Promotes A Healthy Immune System;
Contains phenolic compounds and isobutylamides which
have been shown to promote overall wellness; Stimulates
the immune system; Offers concentrated support in keeping
the body healthy.

Name of Dietary Supplement:
Statement of Nutritional Support:

Eyebright Herb
Promotes Healthy Eye Function

Name of Dietary Supplement:
Statement of Nutritional Support:

Fenugreek Seed
Promotes Digestive Health;
Soothes the colon due to its properties as a natural lubricant
for the digestive tract mucosa; Popular for nursing mothers
since it promotes milk production.



Name of Dietary Supplement:
Statement of Nutritional Support:

Ginger Rhizome
Promotes Healthy Digestion;
Provides excellent natural support for gastrointestinal health

Name of Dietary Supplement:
Statement of Nutritional Support:

Ginseng Root, American
Promotes Adaptation to Stress;
Helps to promote mental and physical calmness

Name of Dietary Supplement:
Statement of Nutritional Support:

Ginseng Root, Korean
Promotes Mental and Physical Vigor;
Considered a "yang" tonic in Chinese medicine, and is most frequently used when an extra boost of energy is desired

Name of Dietary Supplement:
Statement of Nutritional Support:

Ginseng Root, Siberian
Promotes Endurance;
A potent adaptogen; Believed to promote longevity and endurance; Enhances mental and physical performance

Name of Dietary Supplement:
Statement of Nutritional Support:

Goldenseal Root
Promotes Healthy Mucous Membranes;
Helps digestion and supports liver function

Name of Dietary Supplement:
Statement of Nutritional Support:

Gotu Kola Herb
Promotes Overall Wellness;
Has been used in both China and India for thousands of years as a tonic to help balance the effects of aging.

Name of Dietary Supplement:
Statement of Nutritional Support:

Hawthorn Berry
Promotes Cardiovascular Health;
Helps sustain a healthy heart

Name of Dietary Supplement:
Statement of Nutritional Support:

Horsetail Grass
Promotes Healthy Skin & Nails

Name of Dietary Supplement:
Statement of Nutritional Support:

Hyssop Herb
Promotes Respiratory Health;
Helps to relax the bronchial muscles

Name of Dietary Supplement:
Statement of Nutritional Support:

Kava Kava Root
Promotes Relaxation;
Helps reduce nervousness



Name of Dietary Supplement:	Kelp Thallus
Statement of Nutritional Support:	Promotes A Healthy Thyroid
Name of Dietary Supplement:	Licorice Root
Statement of Nutritional Support:	Soothes Mucous Membranes
Name of Dietary Supplement:	Muira Puama Bark
Statement of Nutritional Support:	Promotes Sexual Energy
Name of Dietary Supplement:	Mullein Leaf
Statement of Nutritional Support:	Promotes Respiratory Balance
Name of Dietary Supplement:	Nettle Leaf
Statement of Nutritional Support:	Promotes Upper Respiratory Health; Nutritive tonic traditionally used to balance both upper respiratory health and the urinary system
Name of Dietary Supplement:	Oil of Oregano Herb
Statement of Nutritional Support:	Promotes a Healthy Immune System; Broad range of benefits on the body; Stimulates immune health
Name of Dietary Supplement:	Pau d'arco Inner Bark
Statement of Nutritional Support:	Promotes Immune Support
Name of Dietary Supplement:	Red Clover Tops
Statement of Nutritional Support:	Promotes Female Hormonal Balance; Has been traditionally used for detoxification; Beneficial in balancing female hormones, especially in menopausal women
Name of Dietary Supplement:	Red Raspberry Leaf
Statement of Nutritional Support:	Promotes Female Balance; Traditionally used as an astringent to tone mucous membranes
Name of Dietary Supplement:	Reishi Mushroom Mycelia
Statement of Nutritional Support:	Promotes Immune Function





Name of Dietary Supplement: **Saw Palmetto Berry**
Statement of Nutritional Support: Promotes Prostate Wellness
Promotes urine flow and prostate health

Name of Dietary Supplement: **Senna Leaf**
Statement of Nutritional Support: Promotes A Laxative Action

Name of Dietary Supplement: **Slippery Elm Bark**
Statement of Nutritional Support: Promotes Gastrointestinal Health;
Traditionally used as a demulcent to soothe mucous membranes

Name of Dietary Supplement: **Spirulina**
Statement of Nutritional Support: Promotes A Healthy Body

Name of Dietary Supplement: **Valerian Root**
Statement of Nutritional Support: Promotes A Tranquil Sleep;
Calms the body and encourages relaxation; Promotes sleep.

Name of Dietary Supplement: **Vitex (Agnus-Castus) Chastetree Berry**
Statement of Nutritional Support: Promotes Female Balance

Name of Dietary Supplement: **Astragalus Root, Standardized**
Statement of Nutritional Support: Promotes A Healthy Body
Invigorates vital energy (qi); Maintains wellness

Name of Dietary Supplement: **Bilberry, Standardized**
Statement of Nutritional Support: Promotes Eye Health;
Rich source of anthocyanosides, flavanols believed to be responsible for the herb's beneficial properties in promoting overall eye health; Flavanols contain potent antioxidant properties, and play a key role in building healthy connective tissue, improving circulation and maintaining normal night time vision

Name of Dietary Supplement: **Black Cohosh, Standardized**
Statement of Nutritional Support: Promotes Female Hormonal Balance





Name of Dietary Supplement: **Cat's Claw Inner Bark, Standardized**
Statement of Nutritional Support: Promotes Immune Function;
Traditionally used to promote digestion, enhance immune function and detoxify the body

Name of Dietary Supplement: **Dong Quai Root, Standardized**
Statement of Nutritional Support: Promotes Female Balance;
Well-recognized for its positive actions on helping to regulate the female system and balance hormones

Name of Dietary Supplement: **Echinacea Root, Standardized**
Statement of Nutritional Support: Promotes A Healthy Immune System
Contains phenolic compounds and isobutylamides which have been shown to promote overall wellness; Stimulates the immune system; Offers concentrated support in keeping the body healthy

Name of Dietary Supplement: **Echinacea and Olive Leaf, Standardized**
Statement of Nutritional Support: Promotes Immune Health;
Well-known for its positive actions on the body's natural defense system; Olive Leaf extract has strong immune-enhancing properties; Offers a more advanced level of antioxidant support

Name of Dietary Supplement: **Feverfew Herb, Standardized**
Statement of Nutritional Support: Promotes Head Comfort

Name of Dietary Supplement: **Ginger Rhizome, Standardized**
Statement of Nutritional Support: Promotes Healthy Digestion;
Provides excellent natural support for gastrointestinal health

Name of Dietary Supplement: **Ginkgo Leaf, Standardized**
Statement of Nutritional Support: Promotes Cerebral Circulation;
Promotes healthy circulation to the brain and to the extremities; Herb serves as a potent antioxidant; Has broad range of benefits on the body

Name of Dietary Supplement: **Ginseng Root, Siberian, Standardized**
Statement of Nutritional Support: Promotes Endurance;
A potent adaptogen; Believed to promote longevity and endurance; Enhances mental and physical performance



Name of Dietary Supplement:	Gotu Kola Herb, Standardized
Statement of Nutritional Support:	Promotes Overall Wellness; Has been used in both China and India for thousands of years as a tonic to help balance the effects of aging
Name of Dietary Supplement:	Grape Seed Standardized
Statement of Nutritional Support:	Promotes Antioxidant Activity
Name of Dietary Supplement:	Green Tea Leaf, Standardized
Statement of Nutritional Support:	Combats Free Radicals; Excellent source of bio-flavonoids and rich in antioxidants, which are recognized for their roles in neutralizing free radicals; Helps promotes weight loss
Name of Dietary Supplement:	Hawthorn Leaf, Standardized
Statement of Nutritional Support:	Promotes Cardiovascular Health; Helps to sustain a healthy heart
Name of Dietary Supplement:	Horsechestnut Seed, Standardized
Statement of Nutritional Support:	Promotes Healthy Leg Circulation; Improves tone of veins and increases blood flow
Name of Dietary Supplement:	Kava Kava Rhizome, Standardized
Statement of Nutritional Support:	Promotes Relaxation; Helps reduce nervousness
Name of Dietary Supplement:	Maitake Bio-Beta-Glucan™, Standardized
Statement of Nutritional Support:	Promotes Immune Function
Name of Dietary Supplement:	Milk Thistle Seed, Standardized
Statement of Nutritional Support:	Promotes Healthy Liver Function; Supports and protects the liver
Name of Dietary Supplement:	OleoPein® Olive Leaf, Standardized
Statement of Nutritional Support:	Promotes A Healthy Body; Promotes overall wellness; Powerful antioxidant with a broad-range of immune-enhancing properties
Name of Dietary Supplement:	Passionflower, Standardized
Statement of Nutritional Support:	Promotes Tranquility; Supports relaxation; Promotes sleep





Name of Dietary Supplement:	Red Clover Tops, Standardized
Statement of Nutritional Support:	Promotes Female Hormonal Balance; Traditionally used for detoxification; Beneficial in balancing female hormones, especially in menopausal women
Name of Dietary Supplement:	Reishi Mushroom, Standardized
Statement of Nutritional Support:	Promotes Immune Function
Name of Dietary Supplement:	Saw Palmetto Berry, Standardized
Statement of Nutritional Support:	Promotes Prostate Wellness; Promotes urine flow and prostate health
Name of Dietary Supplement:	Soy Isoflavone Seed, Standardized
Statement of Nutritional Support:	Promotes Female Balance; Contains strong antioxidant properties
Name of Dietary Supplement:	St. John's Wort Herb, Standardized
Statement of Nutritional Support:	Promotes Emotional Balance; Herb has positive actions on mood
Name of Dietary Supplement:	St. John's Wort Herb, Super Standardized
Statement of Nutritional Support:	Promotes A Positive Outlook; Helps stabilize emotional health
Name of Dietary Supplement:	Valerian Root, Standardized
Statement of Nutritional Support:	Promotes A Tranquil Sleep
Name of Dietary Supplement:	White Willow Bark, Standardized
Statement of Nutritional Support:	Promotes Head Comfort
Name of Dietary Supplement:	White Willow with Feverfew, Standardized
Statement of Nutritional Support:	Promotes Head Comfort
Name of Dietary Supplement:	Wild Yam Root, Standardized
Statement of Nutritional Support:	Promotes Female Health
Name of Dietary Supplement:	Acidophilus
Statement of Nutritional Support:	Helps support a "friendly flora" environment in the colon



Name of Dietary Supplement:	Acidophilus-Bifidus
Statement of Nutritional Support:	Acidophilus helps support a "friendly flora" environment in the colon; Bifidus further helps the colon produce B-vitamins; Supports both the intestinal tract and the immune system
Name of Dietary Supplement:	B-Hi B Homocysteine Formula
Statement of Nutritional Support:	Balances homocysteine levels
Name of Dietary Supplement:	B-Stress with Herbs
Statement of Nutritional Support:	Promotes calmness; Supports the function of the adrenal glands; Helps the body adapt to stress; Promotes relaxation of the mind and body while generating a sense of well-being
Name of Dietary Supplement:	Bromelain Plus
Statement of Nutritional Support:	Features Bromelain, a digestive enzyme from pineapple
Name of Dietary Supplement:	Carotene Plus 25,000 I.U.
Statement of Nutritional Support:	Well-rounded support
Name of Dietary Supplement:	Charcoal (Activated)
Statement of Nutritional Support:	Promotes Natural Relief of Gas; Natural internal detoxifier popularly used to help cleanse the body of unwanted materials that can lead to putrefaction and gas or excess flatus
Name of Dietary Supplement:	CoQ-10 30 mg
Statement of Nutritional Support:	Promotes Cardiac Health; Widely used for its numerous benefits on the body; Helps the body produce energy; Balances heart function; Contains powerful antioxidant properties; Essential for neutralizing free radicals
Name of Dietary Supplement:	CoQ-10 50 mg
Statement of Nutritional Support:	Promotes Cardiac Health; Widely used for its numerous benefits on the body; Helps the body produce energy; Balances heart function; Contains powerful antioxidant properties; Essential for neutralizing free radicals
Name of Dietary Supplement:	CoQ-10 60 mg
Statement of Nutritional Support:	Promotes Cardiac Health; Widely used for its numerous benefits on the body; Helps the body produce energy; Balances heart function; Contains powerful antioxidant properties; Essential for neutralizing free radicals



- Name of Dietary Supplement: **CoQ-10 75 mg**
Statement of Nutritional Support: Promotes Cardiac Health;
Widely used for its numerous benefits on the body; Helps the body produce energy; Balances heart function; Contains powerful antioxidant properties; Essential for neutralizing free radicals
- Name of Dietary Supplement: **CoQ-10 120 mg**
Statement of Nutritional Support: Promotes Cardiac Health;
Widely used for its numerous benefits on the body; Helps the body produce energy; Balances heart function; Contains powerful antioxidant properties; Essential for neutralizing free radicals
- Name of Dietary Supplement: **E-400 IU, Natural**
Statement of Nutritional Support: A naturally occurring antioxidant that is found inside cells; Needed for maintenance and protection of healthy cells and tissues
- Name of Dietary Supplement: **EPA Fish Oil – EPA/DHA blend, 1,000 mg**
Statement of Nutritional Support: Provides Omega-3 fatty acids often deficient in the diet; Important for healthy cell membrane formation as well as for balanced hormones and production of series 3 prostaglandins
- Name of Dietary Supplement: **Ester-C® with Bioflavonoids & Rose Hips**
Statement of Nutritional Support: Provides a high level of immune support; Ester-C® has a long acting effect within the body; Bioflavonoids are well-known for their ability to work synergistically with Vitamin C
- Name of Dietary Supplement: **Evening Primrose Oil, 500 mg**
Statement of Nutritional Support: An essential fatty acid needed by the body for balanced hormones and proper formation of cell membranes, lining of the arteries and joint tissue
- Name of Dietary Supplement: **Flaxseed Oil, 1,000 mg**
Statement of Nutritional Support: High in Omega-3 fatty acids, which is important for healthy cell membrane formation as well as for balanced hormones and production of series 3 prostaglandins
- Name of Dietary Supplement: **Glucosamine Plus Chondroitin**
Statement of Nutritional Support: Promotes joint wellness and joint health




Name of Dietary Supplement: **Glucosamine Plus Gymnema**
Statement of Nutritional Support: Promotes Healthy Cartilage

Name of Dietary Supplement: **Lycopene 5 mg**
Statement of Nutritional Support: Combats Free Radicals

Name of Dietary Supplement: **Selenium, 100 mcg**
Statement of Nutritional Support: Provides Antioxidant Support;
Supports the immune system

Name of Dietary Supplement: **Selenium/Natural Vitamin E with Lycopene**
Statement of Nutritional Support: High level of antioxidant activity

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statement(s) is (are) truthful and not misleading.

By 
Frank D'Amelio Jr.
President